Information for Healthcare Professions
Varenicline (marketed as Chantix)

FDA ALERT [2/1/2008]: FDA is issuing this Alert to highlight important revisions to the WARNINGS and PRECAUTIONS sections of the full prescribing information for Chantix regarding serious neuropsychiatric symptoms.

Serious neuropsychiatric symptoms have occurred in patients taking Chantix. These symptoms include changes in behavior, agitation, depressed mood, suicidal ideation, and attempted and completed suicide. While some patients may have experienced these types of symptoms and events as a result of nicotine withdrawal, some patients taking Chantix who experienced serious neuropsychiatric symptoms and events had not yet discontinued smoking. In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following withdrawal of Chantix therapy.

FDA first informed the public about the possibility of serious neuropsychiatric symptoms in the November 20, 2007 *FDA Early Communication About an Ongoing Safety Review*. At that time, information about serious neuropsychiatric symptoms in patients taking Chantix was added to the POST-MARKETING EXPERIENCE section of the prescribing information. As FDA's review of the issue has progressed, it appears increasingly likely that there is an association between Chantix and serious neuropsychiatric symptoms. As a result, FDA requested that Pfizer, the manufacturer of Chantix, elevate the prominence of this safety information to the WARNINGS and PRECAUTIONS sections of the Chantix prescribing information. In addition, FDA is working with Pfizer to finalize a Medication Guide for patients.

This information reflects FDA's current analysis of data available concerning this drug. FDA is not advising practitiones to discontinue prescribing the product and intends to provide updated information when it becomes available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program and complete a form on line at http://www.fda.gov/medwatch/report/hcp.htm or report by fax to 1-800-FDA-0178, by mail using the postage-paid address form provided on line, or by telephone to 1-800-FDA-1088.

At the request of FDA, the Chantix full prescribing information includes new information in the WARNINGS and PRECAUTIONS sections about the possibility of serious neuropsychiatric

symptoms (changes in behavior, agitation, depressed mood, and suicidal ideation and behavior) in patients taking Chantix. FDA is working with Pfizer, the manufacturer of Chantix, to finalize a Medication Guide for patients.

Recommendations and Considerations for Healthcare Professionals

- **Healthcare providers should monitor all patients taking Chantix for symptoms of serious neuropsychiatric symptoms.** Symptoms include changes in behavior, agitation, depressed mood, suicidal ideation, and suicidal behavior. These symptoms have sometimes occurred in patients without pre-existing psychiatric illness and have worsened in some patients with pre-existing psychiatric illness treated with Chantix. In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following withdrawal of Chantix therapy.

- **Patients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder, may experience worsening of their pre-existing psychiatric illness while taking Chantix.** Patients with serious psychiatric illness did not participate in the pre-marketing studies of Chantix. The safety and efficacy of Chantix in these patients has not been established.

- **While Chantix has demonstrated clear evidence of efficacy, it is important to consider these safety concerns and alert patients about these risks.**

Information for the patient: *Physicians who prescribe Chantix should discuss with their patients, patients' families, and caregiver the following:*

- **Tell the doctor about any history of psychiatric illness prior to starting Chantix.** Patients taking Chantix have experienced worsening of current psychiatric illness, even if it is currently under control, and the reoccurrence of previous psychiatric illness.
- **Be alert to changes in mood and behavior.** Symptoms include strange thoughts or behaviors, depressed mood, and thinking about or attempting suicide.
- **Immediately report changes in mood and behavior to the doctor**.
- **Vivid, unusual, or strange dreams may occur while taking Chantix.**

Background Information and Data

FDA first informed the public about the possibility of serious neuropsychiatric symptoms in the November 20, 2007 *FDA Early Communication About an Ongoing Safety Review*. At that time, information about serious neuropsychiatric symptoms in patients taking Chantix was added to the POST-MARKETING EXPERIENCE section of the prescribing information. As FDA's review of the data has progressed and FDA has received additional information, it has become increasingly likely that there is an association between Chantix and serious neuropsychiatric symptoms. As a result, FDA requested that Pfizer, the manufacturer of Chantix, add the information to the WARNINGS and PRECAUTIONS sections of the Chantix prescribing information so that healthcare professionals and patients can be more alert to these issues [insert link to label]. In addition, FDA is working with Pfizer to finalize a Medication Guide for patients.

FDA will update healthcare professionals about new information from FDA's continuing review of the data or new information that it receives on Chantix and serious neuropsychiatric

symptoms. FDA may consider additional regulatory action as the data review and conclusions warrant.

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